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| APPLICATION NO.                                       | FILING DATE | FIRST NAMED INVENTOR  | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|---|-------------|-----------------------|---------------------------------|-----------------------------|
| 10/550,477  | 08/22/2006  | Torsten Branderburger | 05116835                        | 1954                        |
| 26565   | 7590        | 06/08/2010            |                                 |                             |
| MAYER BROWN LLP<br>P.O. BOX 2828<br>CHICAGO, IL 60690 |             |                       | EXAMINER<br>MARCETICH, ADAM M   |                             |
|   |             |                       | ART UNIT<br>3761                | PAPER NUMBER                |
|   |             |                       | NOTIFICATION DATE<br>06/08/2010 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

|  |  |   |  |
|--|--|---|--|
| <p align="center"><b>Advisory Action</b><br/><b>Before the Filing of an Appeal Brief</b></p> | <p><b>Application No.</b><br/>10/550,477</p> | <p><b>Applicant(s)</b><br/>BRANDERBURGER ET AL.</p> |  |
|  | <p><b>Examiner</b><br/>Adam Marcetich</p>    | <p><b>Art Unit</b><br/>3761</p>                     |  |

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 01 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: 1-20.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

/Leslie Deak/  
Primary Examiner, AU 3761

/Adam Marcetich/  
Examiner, Art Unit 3761

Continuation of 3. NOTE:

The amended claims filed 01 June 2010 are not being entered since they would require further search and consideration. Claims 1 and 11 have been amended to include the limitation of a connecting part "that is an injection-molded component."

Examiner had not considered these limitations in the original search. For example, the claims were interpreted more broadly to include components including tubing, without limiting a method of forming. Therefore, this limitation would require additional resources on behalf of the Examiner and is therefore not being entered.

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's arguments filed 01 June 2010 have been fully considered but they are not persuasive.

Applicant notes that Strobel lacks a connector having a non-circular cross-section and instead teaches a clamp that can be used on a delivery tube to ensure that during fluid delivery there is no back flow through the delivery tube back into the bag. Applicant reasons that motivation is lacking to modify Strobel, since the delivery tube of Strobel is already flexible and can be clamped. Examiner finds motivation to modify Strobel, since Strobel calls for clamping and Imer demonstrates that a non-circular cross section is effective to ensure that a clamp occludes a tubing portion.

Applicant contends that Strobel teaches away from the present invention, since Strobel preserves sterility by not puncturing or inserting an object into the bag. Applicant reasons that inserting an object would destroy the teachings of Strobel by compromising sterility. Examiner notes that inserting a probe or connector into tube 5 does not preclude a sterile connection, since tube 5 is downstream of bag 2. Additionally, Strobel calls for a coupling, namely cap 24. Inserting a luer connector does not puncture bag 2 or preclude sterility, since fluid flows downstream from bag 2 when dispensed.

Applicant reasons that Imer fails to remedy the deficiencies of Strobel, since Imer does not puncture or insert an object into a bag. Examiner instead cites Strobel as suggesting a connection port at cap 24, and cites Fowles as teaching a self-sealing membrane for coupling with a spike.

Examiner notes that the limitation of an injection-molded connector part has not been entered, since it would change the scope of the claims as discussed above.